

Appl. No. 09/147,693
Amdt. Dated Nov. 3, 2003
Reply to Final Office Action of June 3, 2003

REMARKS

Claims 38-45, 49-65, 69-72, and 77-78 are pending in the instant application. By this Amendment, Applicants have amended claims 63-65 and 71-72, to address the Examiner's concerns, as set forth in the June 3, 2003 Final Office Action. These claims now recite an "immunogenic" composition rather than a "vaccine" composition. Applicants have also amended claims 39 and 49 to correct minor typographical errors. Support for the claim amendments can be found in the specification and claims as originally filed. Specifically, support for the amendments to claims 63-65 and 71-72 can be found at page 8-11, *inter alia*, of the specification. The present Amendment introduces no new matter, and thus, its entry is respectfully requested.

June 3, 2003 Final Office Action:

Examiner's Rejection under 35 U.S.C. §112, first paragraph:

The Examiner maintained the rejection of claims 63-65 and 71-72 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

Specifically, the Examiner took the position that the claims are not enabled because vaccine making is a poorly enabled art which relies heavily on a trial and error process for discovery and development. The Examiner stated that the instant claims, drawn to a vaccine, do not provide the necessary information for the making of any vaccine, and thus, to make one would require undue experimentation. The Examiner pointed to the complexity of the invention and the general uncertainty and unpredictability involved in making a vaccine. The Examiner acknowledged,

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however, that the Miller and Gregoriadis publications, previously referred to, indicate the ability of bacterial cells to induce an immunogenic response.

In response, without conceding the correctness of the Examiner's position, but to expedite prosecution of the subject application, Applicants have amended claims 63-65 and 71-72 to recite an "immunogenic" rather than a "vaccine" composition. Applicants assert that these claims as amended are fully enabled by the specification. In that regard, Applicants direct the Examiner's attention to the detailed discussion of the claimed compositions set forth in the specification at pages 8-11. These pages describe how to prepare bacterial ghosts using the operator sequences of the present invention, and note that ghost cells have been known in the art to elicit an immune response. In particular, page 9 refers to the production of "a protective cellular or/and humoral immune response in various animal models." Applicants also note the Examiner's acknowledgment, cited above, that such bacterial cells are able to elicit an immune response, (i.e., the production of antibodies), whether or not systemic immunity occurs. Accordingly, Applicants assert that the claimed immunogenic compositions are fully enabled by the specification. Applicants, therefore, respectfully request that the Examiner reconsider and withdraw the rejection of claims 63-65 and 71-72 under 35 U.S.C. §112, first paragraph.

Allowable Subject Matter

The Examiner has allowed claims 38-45, 49-62, 69, 70, 77, and 78.

Applicants acknowledge and appreciate the allowance of these claims.

In view of the above amendments and remarks, it is believed that the claims satisfy the requirements of the patent statutes and fully address the Examiner's concerns as set forth in the June

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3, 2003 Final Office Action. Reconsideration of the instant application and early notice of allowance therefore are requested. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

Date: November 3, 2003



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